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CERTIFICATE OF TRANSMISSION UNDER 37 CFR §1.8

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Signature: 

* * *

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Schaffner, Carl P., *et al.*

Serial No. 10/630,578

Filed: July 30, 2003

For: COMPOSITIONS OF
EZETIMIBE AND METHODS FOR
THE TREATMENT OF
CHOLESTEROL-ASSOCIATED
BENIGN AND MALIGNANT
TUMORS

Group Art Unit: 1614

Examiner: HENLEY III, RAYMOND J.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

AMENDMENT

In response to the Office Action dated May 24, 2004, the Applicants herein petition the Commissioner for an extension of time under 37 CFR 1.136(a). The Commissioner is duly

authorized to charge the proper fee due under 1.17(a) to Deposit Account No. 50-1943.

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PAGE 6/22 * RCVD AT 10/12/2004 2:14:54 PM [Eastern Daylight Time] * SVR:USPTO-EFXXRF-1/2 * DNIS:8729306 * CSID:1 609 896 1469 * DURATION (mm-ss):06-58

10/630,578

electron transport chain), are affected by HMG-CoA reductase inhibitors. Anti-cancer effects of statins, for example, is currently ascribed in the art to the loss of the isoprenoid modification of signaling proteins. Several recent review abstracts are reproduced in an Appendix attached hereto.⁵ This has been the trend and focus of those skilled in the art. Researchers studying the anti-cancer effects of statins, for example, currently believe that these effects reside in the property of statins to reduce protein prenylation and not do to the ability of these drugs to reduce cholesterol presence (or absorption), *per se*. Thus, the logical extension of this reasoning is to simply state that attacking cholesterol to treat cancer is so unapparent that even though the drugs being tested are known cholesterol inhibitors, other mechanisms, unrelated to cholesterol presence or absorption *per se*, are used to explain the anti-cancer effects of these drugs.⁶

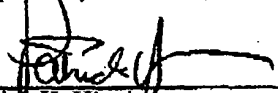
The Applicant accordingly respectfully requests that the Examiner withdraw the rejection under 35 USC §103(a).

* * *

For the foregoing reasons, the Applicant submits that Claims 1-29 are in condition for allowance. Early action toward this end is courteously solicited.

The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1943.

Respectfully submitted,



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DATE: October 12, 2004

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⁵ The Statins As Anticancer Agents, Clin Cancer Res. 2003 Jan;9(1):10-9; Potential Anticancer Effects Of Statins, Endothelium. 2003;10(1):49-58; Potential Antitumor Effects Of Statins (Review), Int J Oncol. 2003 Oct;23(4):1055-69; Studies Of The Isoprenoid-Mediated Inhibition Of Mevalonate Synthesis Applied To Cancer Chemotherapy And Chemoprevention, Exp Biol Med (Maywood). 2004 Jul;229(7):567-85.

⁶ Azetidinone compounds are not contemplated suggested or described anywhere in the art be used as a therapeutic agent to control cholesterol-associated tumors.